

REMARKS

The claims have been amended for clarification. Applicant appreciates the Examiner calling the attention to the undersigned of the necessity of specifying the referent of light emission. In paragraph 2 of claim 1, it has been clarified that the light emission is prevented from those molecules of light emitting moiety (fluorophore) that physically interact with the indicator in the reaction mixture. Only those fluorophores that actually physically interact are prevented from emitting light.

Paragraph 3 has been clarified to note that the decrease in light emission that is determined is that from the reaction mixture, not from the light emitting moiety. In addition, since the light emitting moiety is always a fluorophore, the claim has been amended to indicate this and it is believed that that makes the language simpler.

Claim 4 has also been amended for clarification and new claim 15, which specifies the nature of the enzyme and the substrate is supported in paragraph 16. No new matter is added and entry of the amendment is respectfully requested.

The Invention

The invention is directed to an assay system where an analyte (or an indicator that is generated in proportion to the concentration of an analyte) physically interacts with a fluorescent molecule so as to inhibit or prevent the fluorophore that is physically interacting with indicator from ever emitting light in the first place. In the present specification, in the example set forth in paragraph 16, the indicator generated by the glucose analyte is hydrogen peroxide and the hydrogen peroxide physically interacts with the fluorescent molecule NBD so that any NBD that is being interacted with does not emit fluorescence. This type of quenching is known as “collisional quenching” and is described in Chapter 8 of Lakowicz, J., *Principles of Fluorescence Spectroscopy*,

2nd Ed. (1999) Springer, a copy of which was supplied along with the Response filed 15 October 2007. An additional copy is attached. This article also discloses that hydrogen peroxide is a known “collisional quencher”.

The Rejections Under 35 U.S.C. § 112, Paragraph 1

It is asserted that substitution of the word “prevent” to “inhibit” is new matter.

Respectfully, applicant believes that in the context of the present claims “prevent” and “inhibit” amount to the same thing and that the ability of the collisional moiety to prevent fluorescence is inherent in the physical interaction itself. The claim language has also been clarified to describe this as requiring a physical interaction – *i.e.*, a collision. Collisional quenching is described on page 239 of the above-noted article and more simply described on page 237 thereof. As stated in the left-hand column of page 237, “upon contact, the fluorophore returns to the ground state without emission of a photon.” Thus, the emission is indeed prevented.

It is settled that an inherent property may be claimed explicitly even though it is not articulated in the specification. For example, in *Kennecott Corp. v. Kyocera Int’l, Inc.*, 835 F2d 1419, 5 USPQ2d 1194 (Fed. Cir. 1987), the claims were directed to sintered compositions that had equiaxed microstructures. The words “equiaxed microstructures” did not appear in the specification of the parent application from which priority was claimed. However, because the equiaxed microstructures were inherently present in the sintered composition described in the parent, priority was granted.

Similarly, here, as noted in the attached article, in collisional quenching, which results from physical interaction, the emission of a photon never occurs. Thus, fluorescence is prevented. Accordingly, introduction of the word “prevent” is not new matter.

The rejection is also applied under § 112, paragraph 2, based on apparent skepticism that light would not be emitted. However, this is contradicted by the explanation of collisional quenching in the attached article.

In the end, applicant does not himself believe that it much matters whether the word “prevent” or “inhibit” is used; in either case, this can be distinguished from both the Morris document previously made the basis for rejection and the newly cited Maggio reference. Both clearly refer to what was called in the attached article “apparent” quenching (see page 237, left-hand column).

Applicant appreciates the indication at the interview that the claims as presently clarified are free of the cited art. However, in order to complete the record, applicant’s formal arguments with respect to Maggio follow.

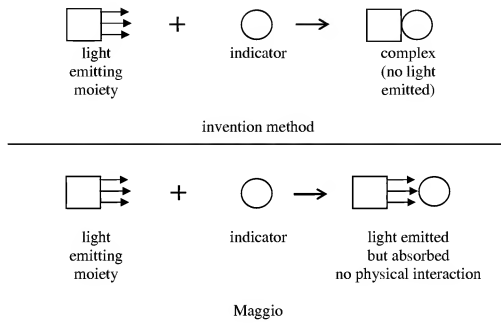
The Rejection Over Maggio (U.S. 4,277,437)

The Office cited column 4, last two paragraphs, as describing quenching as assertedly reading on the invention as claimed. However, this is belied by the definition of “quencher” in column 3, beginning at line 42. This defines a quencher as:

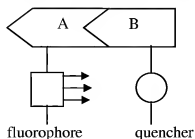
[A] molecule capable of inhibiting the chemiluminescent emission of light, when within a short but non-colliding distance, usually less than about 100 Å, of the chemiluminescer molecule, by accepting the energy which would otherwise be emitted as chemiluminescent light.
(emphasis added)

This “inhibition of emission” refers, of course, to emission of the light from the sample, not emission of the light from the chemiluminescent emitter. Column 15, lines 25-41, make this very clear. Again, it is stated that the quencher molecule is “a chromophore which absorbs light in the wavelength band emitted by the chemiluminescer.”

The difference between the mechanisms required by the present claims and that described in Maggio (and Morris) is illustrated in the following depiction:



As seen, in the invention method, the indicator bumps up against the light-emitting moiety to form a complex and so the light-emitting moiety does not emit any light at all. In the Maggio method, only proximity is achieved, *e.g.*, when a conjugate of the light emitting moiety fluorophore binds to a conjugate of the indicator quencher, and the light-emitting moiety goes on emitting light, but it is absorbed by the indicator. See below where A and B are binding partners:



Thus, the method described by Maggio is inherently different from, and not suggested by, (indeed taught away from) that presently claimed. Therefore, this basis for rejection may be withdrawn.

Conclusion

The consideration given the undersigned by Examiner Gitomer at the interview is very much appreciated. The discussion was most helpful.

The distinction between the invention as claimed and the disclosure of Maggio has been illustrated. In light of this distinction, applicant requests that the presently pending claims, claims 1, 4 and 13-15, be passed to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 527832000420.

Respectfully submitted,

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